



Atty. Dkt. No. 029318-1001

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Douglas HOVEY et al.  
Title: NOVEL FLUTICASONE FORMULATIONS  
Appl. No.: 10/768,194  
Filing Date: 02/02/2004  
Examiner: Unassigned  
Art Unit: 1616

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document, except as noted below, is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.*

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

#### **TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

#### **RELEVANCE OF EACH DOCUMENT**

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date

June 22, 2004

FOLEY & LARDNER LLP

Customer Number: 22428

Telephone: (202) 672-5538

Facsimile: (202) 672-5399

By

Michele M. Simkin

Michele M. Simkin

Attorney for Applicants

Registration No. 34,717

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1

of

3

**Complete if Known**

Application Number	10/768,194
Filing Date	02/02/2004
First Named Inventor	Douglas Hovey
Group Art Unit	1616
Examiner Name	Unassigned
Attorney Docket Number	029318-1001

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A1	4,783,484		VIOLANTE ET AL.	11/08/1988	
	A2	4,826,689		VIOLANTE ET AL.	05/02/1989	
	A3	4,997,454		VIOLANTE ET AL.	03/05/1991	
	A4	5,145,684		LIVERSIDGE ET AL.	09/08/1992	
	A5	5,298,262		NA ET AL.	03/29/1994	
	A6	5,302,401		LIVERSIDGE ET AL.	04/12/1994	
	A7	5,318,767		LIVERSIDGE ET AL.	06/07/1994	
	A8	5,326,552		NA ET AL.	07/05/1994	
	A9	5,328,404		BACON	07/12/1994	
	A10	5,336,507		NA ET AL.	08/09/1994	
	A11	5,340,564		ILLIG ET AL.	08/23/1994	
	A12	5,346,702		NA ET AL.	09/13/1994	
	A13	5,349,957		YUDELSON	09/27/1994	
	A14	5,352,459		HOLLISTER ET AL.	10/04/1994	
	A15	5,399,363		LIVERSIDGE ET AL.	03/21/1995	
	A16	5,401,492		KELLAR ET AL.	03/28/1995	
	A17	5,429,824		JUNE	07/04/1995	
	A18	5,447,710		NA ET AL.	09/05/1995	
	A19	5,451,393		LIVERSIDGE ET AL.	09/19/1995	
	A20	5,466,440		RUDDY ET AL.	11/14/1995	
	A21	5,470,583		NA ET AL.	11/28/1995	
	A22	5,472,683		ILLIG	12/05/1995	
	A23	5,494,683		LIVERSIDGE ET AL.	02/27/1996	
	A24	5,500,204		OSIFO	03/19/1996	
	A25	5,510,118		BOSCH ET AL.	04/23/1996	
	A26	5,518,187		BRUNO ET AL.	05/21/1996	
	A27	5,518,738		EICKHOFF ET AL.	05/21/1996	
	A28	5,521,218		OSIFO	05/28/1996	
	A29	5,525,328		BACON ET AL.	06/11/1996	
	A30	5,534,270		DE CASTRO	07/09/1996	
	A31	5,543,133		SWANSON ET AL.	08/06/1996	
	A32	5,552,160		LIVERSIDGE ET AL.	09/03/1996	
	A33	5,560,931		EICKHOFF ET AL.	10/01/1996	
	A34	5,560,932		BAGCHI ET AL.	10/01/1996	
	A35	5,565,188		WONG ET AL.	10/15/1996	
	A36	5,569,448		WONG ET AL.	10/29/1996	
	A37	5,571,536		EICKHOFF ET AL.	11/05/1996	
	A38	5,573,749		ILLIG	11/12/1996	
	A39	5,573,750		SINGH	11/12/1996	
	A40	5,573,783		DESIENO ET AL.	11/12/1996	
	A41	5,580,579		RUDDY ET AL.	12/03/1996	

**Examiner  
Signature**
**Date  
Considered**

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>		
				Application Number		10/768,194
				Filing Date		02/02/2004
				First Named Inventor		Douglas Hovey
				Group Art Unit		1616
				Examiner Name		Unassigned
Sheet	2	of	3	Attorney Docket Number		029318-1001

U.S. PATENT DOCUMENTS						
	U.S. Patent Document					
	A42	5,585,108		RUDDY ET AL.	12/17/1996	
	A43	5,587,143		WONG	12/24/1996	
	A44	5,591,456		FRANSON ET AL.	01/07/1997	
	A45	5,593,657		RUDDY ET AL.	01/14/1997	
	A46	5,622,938		WONG	04/22/1997	
	A47	5,628,981		LIVERSIDGE ET AL.	05/13/1997	
	A48	5,643,552		ILLIG	07/01/1997	
	A49	5,718,388		CZEKAI ET AL.	02/17/1998	
	A50	5,718,919		RUDDY ET AL.	02/17/1998	
	A51	5,741,522		VIOLANTE ET AL.	04/21/1998	
	A52	5,747,001		WIEDMANN ET AL.	05/05/1998	
	A53	5,776,496		VIOLANTE ET AL.	07/07/1998	
	A54	5,834,025		DE GARAVILLA ET AL.	11/10/1998	
	A55	5,862,999		CZEKAI ET AL.	01/26/1999	
	A56	6,045,829		LIVERSIDGE ET AL.	04/04/2000	
	A57	6,068,858		LIVERSIDGE ET AL.	05/30/2000	
	A58	6,153,225		LEE ET AL.	11/28/2000	
	A59	6,165,506		JAIN ET AL.	12/26/2000	
	A60	6,221,400	B1	LIVERSIDGE ET AL.	04/24/2001	
	A61	6,264,922	B1	WOOD ET AL.	07/24/2001	
	A62	6,267,989	B1	LIVERSIDGE ET AL.	07/31/2001	
	A63	6,270,806	B1	LIVERSIDGE ET AL.	08/07/2001	
	A64	6,316,029	B1	JAIN ET AL.	11/13/2001	
	A65	6,375,986	B1	RYDE ET AL.	04/23/2002	
	A66	6,406,718	B1	COOPER	06/18/2002	
	A67	6,428,814	B1	BOSCH	08/06/2002	
	A68	6,431,478	B1	REED ET AL.	08/13/2002	
	A69	6,432,381	B1	LIVERSIDGE ET AL.	08/13/2002	
	A70	6,582,285	B1	CZEKAI ET AL.	06/24/2003	
	A71	6,592,903	B2	RYDE ET AL.	07/15/2003	
	A72	6,656,504	B1	BOSCH ET AL.	12/02/2003	
	A73	2002/0012675	A1	JAIN ET AL.	01/31/2002	

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	A74	WO	02/098565	A1	ELAN PHARMA INTERNATIONAL LIMITED	12/12/2002		
	A75	GB	2088877	A	GLAXO GROUP LIMITED	06/16/1982		

Examiner  
Signature

Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/768,194
				Filing Date	02/02/2004
				First Named Inventor	Douglas Hovey
				Group Art Unit	1616
				Examiner Name	Unassigned
Sheet	3	of	3	Attorney Docket Number	029318-1001

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>6</sup>
	A76	LINDAHL ET AL., "Characterization of Fluids from the Stomach and Proximal Jejunum in Men and Women", <i>Pharmaceutical Research</i> , Vol. 14, No. 4, pp. 497-502, 1997.		
	A77	Physician's Desk Reference, 57 <sup>th</sup> Edition, pp. 1433, 1438, 1497, 1499, 1522, 1525, 1528, 1532 (2003).		

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.